STANDARD OPERATING PROCEDURE TEMPLATE · INFORMATION MANAGEMENT, LIS AND PRIVACY

# LIS User Access, Passwords and Data Backup

Governing requirement: 45 CFR 164.312 (HIPAA Security Rule)

**Applies to:** ☑ Waived ☑ Moderate complexity ☑ High complexity

| | | | |
|---|---|---|---|
| **Laboratory name** | | **CLIA number** | |
| **Document number** | | **Version** | |
| **Effective date** | | **Next review due** | |
| **Author** | | **Department / section** | |
| **Approved by (laboratory director)** | | **Director signature** | |
| **Approval date** | | **Supersedes document** | |

**Important:** Template only. Before use, this document must be reviewed, adapted to your laboratory's instruments, test systems and the manufacturer's instructions, and approved, signed and dated by the laboratory director. Check current federal, state and accreditation requirements. Not legal advice. Sound Lab Consultants is not affiliated with or endorsed by CMS, CDC, FDA, OSHA, CAP, COLA, The Joint Commission, CLSI or any manufacturer.

## 1. Purpose

To protect electronic patient data.

## 2. Scope

All lab information systems.

## 3. Responsibility

- Laboratory director: approves policies and validations.
- LIS / IT administrator: maintains systems, access and backups and documents changes.
- All staff: protect patient information and report suspected incidents.

## 4. Definitions

**Role-based access:** Permissions based on job role.

## 5. Materials, equipment and records

- User access list
- Backup records

## 6. Procedure

**1.** Create unique user IDs; no shared accounts.

**2.** Assign access by role.

**3.** Remove access promptly on termination.

**4.** Review audit logs **[Frequency]**.

| | |
|---|---|
| **Frequency** | |

**5.** Back up data **[Backup frequency]** and test restores.

| | |
|---|---|
| **Backup frequency** | |

## 7. Quality control

• Review access, audit logs or validation records on the schedule in this SOP and document the review.

## 8. Interpretation, reporting and documentation

• Record the activity, date, result and initials on the form or log, and have the supervisor review records **[Review frequency]**.

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|---|---|
| **Review frequency** | |

• Keep records per the record retention SOP (at least 2 years under 42 CFR 493.1105 unless a longer period applies).

## 9. Limitations and cautions

• This is a generic template. Adapt it to your instruments, test systems, manufacturer instructions, state law and accreditation standards before use.

## 10. References

• HHS, HIPAA Security Rule summary
https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html

## 11. Lab-specific notes

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|---|---|
| **Notes and local requirements** | |

## 12. Revision history

| Version | Date | Description of change | Author | Approved by |
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## 13. Annual review log

Procedures and changes must be approved, signed and dated by the current laboratory director before use (42 CFR 493.1251(d)).

| Review date | Reviewed by | Signature | Changes needed (Y/N) | Comments |
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